

Pesticide Registration

The Registration Process

Before a pesticide may be marketed and used in California, DPR evaluates it thoroughly, under guidelines of the Food and Agricultural Code (FAC), to ensure that it will not harm human health or the environment. Pesticides that pass this scientific, legal, and administrative process are granted a license that permits their sale and use according to requirements set by DPR to protect human health and the environment. This licensing process is called “registration.” A “registrant” is someone who does business in California selling pesticidal chemicals or formulated pesticide products.³ The term “registrant” does not include retail pesticide dealers, but may include manufacturers of the basic, technical-grade pesticidal chemicals; formulators who prepare the end-use products; and distributors who put their own labels on pesticide products purchased from formulators.

The law requires prospective registrants to submit tests and studies of the pesticides to DPR for evaluation. DPR’s Director may decide not to register a pesticide product, or cancel the registration of any product already registered. That action must be based on serious, uncontrollable adverse effects on the environment; greater detriment than benefit to the environment; harm to vegetation, domestic animals, or public health and safety; and uses deemed to hold little or no value.

Several DPR branches participate in pesticide registration to assure that a product used according to label instructions will cause no harm (or “adverse impact”) on nontarget organisms that cannot be reduced (or “mitigated”) with protective measures or use restrictions. The Pesticide Registration Branch coordinates this process and serves as liaison to pesticide registrants.

The registration process begins when applicants submit data to DPR on a product’s toxicology; how it behaves in the environment; its effectiveness against targeted pests (“efficacy”); its hazards to nontarget organisms; its effects on fish and wildlife; the degree of worker exposure, and its chemistry. Several branches with different areas of expertise review the data.

Registration and evaluation includes the following steps:

- The Medical Toxicology Branch reviews toxicology and other studies from the registrant for adequacy and potential adverse effects. If potential adverse health effects are found, the pesticide’s risk potential is studied and a risk evaluation is prepared by the Medical Toxicology and Worker Health and Safety Branches. If the pesticide is a new active ingredient, it is prioritized for risk assessment. (See Chapter 5 for discussion of risk characterization process.)
- In the Pesticide Registration Branch, staff scientists with expertise in chemistry, microbiology, plant physiology, pest/disease prevention, and fish and wildlife biology review required scientific data to determine the effects of pesticides on target pests (efficacy) as well as nontarget effects (that is, effects on species not considered the target pest). The latter includes nontarget effects on plants (phytotoxicity); fish and wildlife hazards (ecotoxicity); impact on endangered species; effects on the environment, e.g., environmental fate, breakdown products, leachability and persistence

The control of pesticides in California is obtained through registration. Manufacturers intending to sell pesticides must register their products and fully comply with the law.

– 1939 Department annual report

³ Because pesticidal chemicals are usually highly concentrated and will not mix easily with water, most are mixed with other ingredients (such as emulsifiers, solvents, wetting agents) before being marketed as end-use products. The prepared, or formulated, mixture is called a formulation.

A material not valuable for its intended purpose, or one which, even when properly used, is detrimental to cultivated vegetation, to domestic animals, or to the public health, will not be registered and can not be sold in California.
 – 1933 Department annual report

(chemistry); pest and disease protection (entomology); and plant pathology. Included is a review to ensure that product residues on harvested commodities will not exceed legal limits when the pesticide is used according to label directions.

- Product labels are reviewed by four branches. Registration Branch reviews labels for compliance with U.S. EPA labeling standards and clarity. Medical Toxicology ensures labels accurately reflect human health hazards indicated by toxicology data. The Pesticide Enforcement Branch reviews labeling to address regulatory concerns — such as whether label requirements can be enforced in the field — before registration. The Worker Health and Safety Branch examines labels to assess the adequacy of use instructions to protect pesticide users and others from overexposure. If any changes are necessary, DPR staff work with the registrant and U.S. EPA to recommend revisions that will satisfy health or environmental concerns. (According to federal law, pesticide label language is under the sole jurisdiction of U.S. EPA. Any changes in label language must be approved by U.S. EPA before the product can be sold in this country. A state cannot require manufacturers to make changes in labels. However, states can refuse to allow registration and hence the possession, sale and use of any pesticide not meeting its own standards.)
- Finally, Environmental Monitoring Branch evaluates pesticide products for potential to contaminate ground or surface water, and Pest Management and Licensing Branch for detrimental impacts on integrated pest management⁴ systems, when appropriate.

DPR also consults with other public agencies on proposed pesticide registrations and more broadly on regulatory policies through routine daily contacts and, more formally, through the Pesticide Registration and Evaluation Committee (PREC). Chaired by the Assistant Director of DPR's Registration and Health Evaluation Division, the PREC meets regularly (typically every two months). It brings together all public agencies with legal jurisdiction on use of pesticides, or whose activities or resources may be affected by use of pesticides. The committee includes representatives of the State Departments of Health Services, Food and Agriculture, Industrial Relations, and Fish and Game; the Structural Pest Control Board; Cal/EPA's Office of Environmental Health Hazard Assessment, State Water Resources Control Board, Air Resources Board, Integrated Waste Management Board, Toxic Substances Control Department; the University of California; U.S. EPA, Region 9; U.S. Department of Agriculture; and the California Agricultural Commissioners and Sealers Association.

The purpose of the PREC is to advise DPR on regulatory development and reform initiatives, evolving public policy and program implementation, and science issues associated with evaluating and reducing risks from the use of pesticides. It also fulfills a critical interagency consultation role mandated by CEQA. (In 2000, the Department's Pesticide Advisory Committee, whose function was overlapped with that of the PREC, was merged with the latter committee.)

Once reviews are completed, a decision to register or deny an application is proposed. If any reviewing DPR branch recommends against registration due to inadequate data, unacceptable studies, or unmitigated adverse effects, the product is not registered until all concerns are resolved, including concerns raised by other State agencies. Proposed decisions to register or deny applications are posted weekly, beginning a 30-day period for public comment before the decision is final.

While State registration parallels the federal program in many respects, there are differences in application. DPR may require additional or different studies than those required by U.S. EPA. These studies include but are not limited to data on worker

⁴ Integrated pest management (IPM) is an ecosystem-based strategy that focuses on long-term prevention of pests or their damage through a combination of techniques such as biological control, habitat manipulation, modification of cultural practices, and use of resistant varieties. Pesticides are used only after monitoring indicates they are needed according to established guidelines, and treatments are made with the goal of removing only the target organism. Pest control materials are selected and applied in a manner that minimizes risks to human health, beneficial and nontarget organisms, and the environment. The IPM approach can be applied to both agricultural and non-agricultural settings, such as the home, garden, and workplace.

exposure, treatment for accidental poisoning, foliar (leaf) residue, indoor exposure potential, hazards to bees, and dust hazard from powdered products.

DPR requires efficacy data be submitted as part of an application for registration. U.S. EPA requires manufacturers to develop such data but waives its submission, except for products with public health uses, such as disinfectants.

DPR also gives specific attention to evaluating pesticide use under California's unique climatic and cultural conditions. Pesticide residues which decay rapidly under warm, humid conditions may persist longer under hot, dry conditions typical in many California agricultural areas. Some crops, such as rice, may be grown with water and land management practices that differ from other areas of the country. Algicides and other pesticides used in swimming pools must reflect the outdoor, year-round use typical of California.

Such differences affect evaluations of product safety and effectiveness. Varied conditions, combined with local use enforcement mechanisms, allow use of some pesticides to be restricted to certain areas of California, as opposed to a statewide ban. This may be accomplished by placing restrictions in regulation; by making a pesticide a restricted material and recommending use restrictions to the County Agricultural Commissioners (*see Chapter 7 for discussion of restricted material permit system*); or by working with the registrant to place California-only instructions on the federally approved label.

DPR sometimes denies registration to products approved by U.S. EPA. The Department may base such decisions on toxicology or environmental studies judged to be inappropriate or inadequate, label instructions that fail to mitigate possible hazards, or inadequate margins of safety. (*See discussion of risk characterizations, Chapter 5.*) DPR has also denied State registration for federally registered products that could not show reasonable effectiveness under California conditions, or which did not meet labeling claims. From its review and evaluation, DPR may also impose use restrictions and mitigation measures beyond those listed on labels, either through regulation or through the restricted materials permit system.

Improving the Process

Harmonization Project with U.S. EPA: A 1993 study of DPR's registration process by consultants Charles M. Benbrook and Deanna J. Marquart (*see the article in this Chapter for information on "Challenge and Change: A Progressive Approach to Pesticide Regulation in California"*) made a series of recommendations, including that DPR explore ways of interacting with U.S. EPA to speed the registration of new, more environmentally benign pesticides. Dr. Benbrook recommended that DPR work cooperatively with U.S. EPA, avoiding duplication of effort and developing specialized expertise tailored to augment that of the federal agency.

In March 1995, DPR and U.S. EPA signed a formal commitment to step up the pace of harmonization, a project begun in 1994 to more closely coordinate the federal and California pesticide regulation programs. Harmonization goals include reducing needless duplication, getting safer products to market faster, and more quickly removing those products from use that pose unacceptable risks. Resources saved by harmonization can then be spent on accelerating the registration of low-risk products.

The agreement between DPR and U.S. EPA included target dates for completion of key phases. The first target date — June 1995 — was met with the two agencies sharing their reviews of acute toxicology data. Passage of the federal Food Quality Protection Act (FQPA) in August 1996, put many harmonization activities on hold while U.S. EPA dealt with its new priorities. As U.S. EPA comes to terms with FQPA, it is refocusing on projects of mutual interest with California. Harmonization efforts have also begun to shift to the world stage with opportunities presented by the North American Free Trade Agreement (NAFTA). It is also critical for DPR to stay abreast of the emerging global approach to risk assessment represented by the Organisation for Economic Cooperation and Development's (OECD) monograph system.

Streamlining Registration: The 1993 *Challenge and Change* report also recommended that DPR reorient its activities toward a risk-driven prioritization theme: getting



DPR may impose use restrictions beyond those listed on the product label.

lower risk products registered more expeditiously and devoting regulatory efforts on higher-risk products and activities.

In 1993, legislation (Chapter 963, AB 771) established an interim registration process that allowed DPR to waive or delay certain data requirements for federally registered pesticides which meet specified criteria. Registration Branch can waive efficacy data and certain ground water studies if Pest Management and Licensing Branch confirms that the product would reduce risks when used in a pest management system. The product must reduce risks to workers, public health or the environment, lessen the risk of pest resistance problems, or reduce a substantial risk of economic loss as a result of a pest infestation for which there is no other feasible control. The registrant must agree to generate the required data. DPR charges an additional \$5,000 fee to cover additional costs involved in this interim registration.

A second interim registration process was established by 1995 legislation (Chapter 608, SB 283) that allows DPR to issue a certificate of “emergency registration” for federally registered products that have been previously used in the State under a Section 18 emergency exemption issued by U.S. EPA. *(A discussion of the Section 18 process concludes this Chapter.)* Once a pesticide is registered federally, it automatically is no longer eligible for a FIFRA Section 18. The legislation established a mechanism to allow the temporary use of the pesticide while the California registration process for that product was being completed. DPR must determine that all required data has been submitted and that it is probable that the product will be registered within a year. The emergency registration may be issued for one year, with an additional year renewal possible. The Department must also certify that there are no indications the product would pose an unacceptable risk to worker safety, and that DPR’s delay in completing a timely review of the data was beyond the control of the registrant.

The Department used recommendations in the *Challenge and Change* report, those of registrants, and its own review of the registration process to identify changes to substantially reduce the time required for product approval, without altering California’s strict standards. During the 1990s, DPR prioritized risk assessments to provide a more effective process for new, reduced-risk active ingredients and also made data review procedures more efficient.

In 1994, to encourage the registration of pesticides that pose lower risks to public health and the environment, DPR began allowing companies to submit applications for registration of microbial, biochemical, and new reduced-risk products to California when they submit applications for federal registration. In 1999, DPR began allowing companies to submit concurrent applications for products classified by U.S. EPA as “public health pesticides” or “antimicrobial pesticides,” provided the product had human health benefits. This expedited registration process was mandated by 1997 legislation (Chapter 428, SB 464) that allowed DPR to waive the submission and/or review of efficacy data for antimicrobial pesticides, if certain criteria were met.

In 1999, the Legislature allocated supplemental funds to the Department to hire additional staff to focus on the registration of reduced-risk pesticides and on reducing the registration backlog.

Ombudsman: In 1993, in response to a recommendation in the *Challenge and Change* report, DPR established an ombudsman position to help solve pesticide registration problems quickly and efficiently. The Ombudsman provides a central contact point for the regulated community, the public, and other government agencies on pesticide registration issues and general aspects of pesticide regulation. On a day-to-day basis the Ombudsman answers questions and acts as a troubleshooter in the investigation and resolution of disputes. By interpreting and clarifying policy issues and identifying problem areas, management is assisted in internal streamlining efforts to increase efficiency and timeliness. The Ombudsman represents the department at the statewide Cal/EPA Ombudsman Forums which allow attendees to obtain information about interdepartmental issues. In addition to general presentations to various groups, the Ombudsman also conducts training workshops for the regulated community. This facilitates understanding of and compliance with the extensive pesticide regulatory process.

In the 1990s, the Department focused on streamlining its program while maintaining California’s high environmental and health standards.

“Challenge and Change” Changing Pesticide Regulation in California

DPR continuously strives to improve its processes and programs while removing bureaucratic obstacles and encouraging creative and environmentally sound pest management practices in California. A 1993 report commissioned by Cal/EPA highlighted DPR’s commitment to quality government.

In *Challenge and Change: A Progressive Approach to Pesticide Regulation in California*, regulatory analysts Dr. Charles Benbrook and Deanna J. Marquart provided an in-depth critique of DPR’s pesticide registration program. While the then-new Department was already working on a number of the goals suggested by Dr. Benbrook, the report helped focus DPR efforts to create a more efficient and effective registration process without compromising California’s environmental standards. Challenge and Change made three general recommendations: (1) change DPR policies and procedures to improve the efficiency of product review and approval; (2) make relative risk of pesticide products and active ingredients the guiding factor in DPR priorities, and (3) use the Department’s regulatory powers to increase influence of biologically-based pesticide control programs, including integrated pest management (IPM).

Toward that goal, DPR established an “IPM Innovator” award program in 1994 to recognize growers and other leaders in alternative methods of pest management. The program distributes information about the latest and most effective IPM techniques, and encourages and coordinates creation of new “innovator” groups.

Other DPR achievements that address recommendations in Challenge and Change include:

- Appointing a Pesticide Registration Ombudsman.
- Providing training sessions for registrants.
- Reviewing registration applications for biopesticides and other reduced-risk pesticides concurrent with their submission to U.S. EPA.
- Implementing legislation that helps expedite registration of products that fit into pest management systems.
- Developing guidelines for risk and exposure assessment; participating in Cal/EPA effort to establish uniformity in risk assessment.
- Facilitating policy discussions in public advisory committees.
- Participating in national and international development of exposure assessment guidelines.
- Focusing scientific and regulatory efforts in risk reduction measures on certain high-risk use patterns.
- Initiating projects to reduce risk incrementally and set pest management research priorities.
- Conducting workshops to address regulatory barriers to reduced-risk pest management strategies.
- Proposing regulations to require continuing education in reduced-risk pest management.

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Registration of Pest Control Devices

The structural pest control industry sponsored 1998 legislation (Chapter 651, AB 1134) which created a program to require the registration of devices used to control wood-destroying pests. Under the law, DPR must review the efficacy and safety of each device before registration. As of July 1, 2001, it is unlawful to sell, possess, or use a structural pest control device in California, unless it is registered by DPR.

The Structural Pest Control Device Program is enforced by DPR, the CACs, and the Department of Consumer Affairs' Structural Pest Control Board (SPCB). DPR has authority to take registration and enforcement actions against parties who violate device statutes. At the local level, the CAC is authorized to levy civil penalties for violation of device statutes. In addition, the SPCB may take disciplinary action against its licensees for violations of device statutes.

Funding for the device program is derived from a fee assessed by SPCB for each structural fumigation performed in California. Those fees are placed in the Structural Pest Control Device Fund, and are used to support structural pest control device activities performed by DPR and SPCB.

Experimental Uses and Research Authorizations

Before federal or state regulators register a pesticide, they must collect data on how it behaves under field conditions, including factors such as efficacy, environmental fate, and potential worker exposure. In addition, DPR requires California-specific data. During the summer growing season when farmers apply many pesticides, most states have significant rainfall, in contrast to California's typically dry summers. Because field studies must be conducted to collect these data, permit processes have been set up under both federal and State law to allow limited, experimental uses of pesticides.

Under FIFRA, U.S. EPA may grant registrants experimental permits for new uses of registered or unregistered pesticides. Products granted a federal experimental use permit may then be granted conditional registration — limited to experimental uses — in California, provided certain data requirements are met. If the test product contains an active ingredient already registered for other uses in the State, registrants must submit data on acute toxicity and analytical methods to detect residues in the treated commodity. If the product contains a new active ingredient unregistered in California, chronic health effects studies are also required.

Federal experimental use permits are not required for most experiments on less than 10 acres, unless they involve certain genetically-engineered microbial pesticides. Conducting these small-scale experiments in California, however, requires a research authorization from DPR's Pesticide Registration Branch. Approximately 600 to 800 research authorizations are issued yearly, and about two-thirds involve compounds already registered for other uses in California. Most research authorizations are for 10 acres or less, although experimental plots may extend up to 100 acres, provided the use is federally registered.

In applying for a research authorization, the applicant must specify the pesticides, treated crop or site, size of the trials, rates to be used, any existing tolerances, and proposed disposition for the treated crop. If the pesticide is not currently registered for any use, the applicant must supply information on acute health effects. DPR may require additional data as necessary to assess potential adverse effects to workers, the public, or the environment. If there is no applicable residue tolerance for the crop, the research authorization requires the crop to be destroyed.

DPR and County Agricultural Commissioners administer various other restrictions, designed to provide close regulatory control of experimental uses of pesticides.

Exemptions from Registration Requirements

Sterilants Used in Medical Devices: Among the provisions of the 1996 federal Food Quality Protection Act was to transfer jurisdiction over certain liquid chemical sterilant products from U.S. EPA to the U.S. FDA. Based on the law, U.S. FDA took over regulation of sterilants used on critical or semicritical medical devices. These products

Continuous experimentation and investigation in the field of pest control by competent technical workers result in the appearance of many new insecticides, fungicides, and other agricultural chemical products, as well as improvements in older ones.
— 1939 Department annual report

were exempted from FIFRA and no longer subject to federal pesticide registration requirements (since U.S. FDA does not “register” the products it regulates).

Legislation (Chapter 530, Statutes of 1997, SB 365) designed to harmonize California law with federal law authorized DPR to exempt from California registration requirements any liquid chemical sterilant product intended for use on critical or semicritical medical devices, that has been exempted from regulation by the U.S. EPA and has been approved for sale by U.S. FDA.

Section 25(b) Exemptions: In 2000, DPR adopted regulations exempting certain kinds of minimum-risk pesticides from registration requirements. The regulations were authorized by 1997 legislation (Chapter 691, SB 445) that allowed DPR to exempt certain chemicals from registration after U.S. EPA had done so. Most exempt chemicals are low-risk substances that have a wide range of other, nonpesticidal uses as foods, medicines, or household items. They include substances such as garlic, peppermint, rosemary, corn oil, cedar chips, and castor oil. DPR scientific staff evaluated each substance for potential hazards before placing it in the exemption regulation. The products cannot make claims to control or mitigate microorganisms that pose a threat to human health, including but not limited to disease-transmitting bacteria or viruses. Claims that specify possible control of disease carried by insects or rodents are also prohibited. In addition, the product must not include any false or misleading statements. Products exempted from registration still remain under DPR oversight. The Department continues to require manufacturers to submit reports of any adverse effects from the use of the exempted products so that DPR can reassess exemptions if necessary.

Section 24(c) Special Local Need Registrations and Section 18 Emergency Exemptions: Federal law allows states to issue certain special registrations and emergency exemptions for pesticide use under specific circumstances. Under criteria outlined in Section 18 of FIFRA (emergency exemptions) and Section 24(c) (special local need, or SLN registrations), these uses can be approved outside the lengthy regular U.S. EPA registration process. Criteria include data to support the use, and justification that no other registered products are available to meet the emergency situation or special local need. These special registrations and emergency exemptions have limitations on use and require special labeling.

A Section 24(c) can be requested by either the manufacturer as the first party or by a third party such as a grower association. A Section 18 can only be requested by a third party such as a grower association or County Agricultural Commissioner. The supporting documentation and justification are supplied by growers, pest control advisers, County Agricultural Commissioner offices, university, and other knowledgeable experts.

Section 24(c) Special Local Need registrations: These are state-specific registrations, through which states can register a new pesticide product for any use, or additional use of a federally-registered product, as long as there is both a demonstrated “special local need” for such a product, and a tolerance, exemption from a tolerance, or another clearance under the Federal Food, Drug and Cosmetic Act has been established. The special local need can be in a region of the state or can cover the entire state, and can be for a food or nonfood use. If for a food or feed use, a residue tolerance (or exemption from tolerance) must already be established for the active ingredient on that commodity. (Sometimes a group tolerance for similar kinds of crops is already in place.) Residue data to support the proposed use rates and method of application must be available for review. Some reduced-risk active ingredients, such as *Bacillus thuringiensis* (B.t.), are exempt from the tolerance requirement.

The special local need must be justified and supported by knowledgeable experts and there can be no registered products available to meet the need. Once issued, an SLN remains in effect indefinitely until withdrawn by the registrant, manufacturer or DPR, or until U.S. EPA cancels the use. (DPR issues approximately 100 SLNs each year.)

Section 18 emergency exemptions: A state can issue a Section 18, after approval by U.S. EPA, to meet an emergency pest problem. The emergency need can occur in a region of the state or in the entire state and is for food or feed use only. Because the use of exemptions from registration should be kept to a minimum, Section 18 applications undergo intensive scrutiny by DPR. Each year, DPR rejects several Section 18 applications.



We should not encourage spraying or get into the habit of spraying ourselves unless we know just exactly what we are spraying for. As a general rule, the man who sprays and doesn't know just exactly what he is spraying for, or what he ought to use, is not getting results in his spraying. Spraying requires a knowledge of the pests which are on the trees. It requires a thorough knowledge of insecticides and fungicides, and until we have the knowledge we cannot do spraying that is altogether effective.

– 1922 Department annual report

Registration of products before they are offered for sale eliminates those that are worthless or dangerous; examination of labeling and advertising corrects misrepresentation; and analysis of materials assures conformity with the guaranteed composition.
 – 1950 Department annual report

Extensive documentation of the emergency pest problem must accompany a Section 18 request, including detailed information on the nature of the emergency, costs of control, past yields, projected losses, a five-year economic profile for the crop, and evidence of the lack of registered, available alternative pest control practices. DPR routinely contacts university researchers and other expert sources to verify the justification. The request must also include any available residue data to support a tolerance level. (Until 1996, an “action level” for the amount of residue allowed at harvest was all that was required, but the Food Quality Protection Act of 1996 required that a time-limited residue tolerance be issued with each Section 18.) After DPR’s scientific review of the residue, chemistry, toxicology, and efficacy data — and confirmation of the emergency need — the request is forwarded to U.S. EPA with a proposed time-limited tolerance. (DPR staff prepares the scientific evaluation for many Section 18 tolerances. U.S. EPA has relied on DPR’s expertise for those reviews, reducing the time it takes to issue a Section 18.)

When it approves the Section 18, U.S. EPA also establishes a time-limited tolerance. If the nature of the pest emergency allows no time for U.S. EPA’s review, DPR may issue a “crisis” Section 18. This allows the chemical to be used before a tolerance is set. However, because crops cannot be harvested until U.S. EPA issues a tolerance, DPR does not issue crisis Section 18s until convinced, after consultation with U.S. EPA, that the federal agency will grant the tolerance. Nonetheless, DPR alerts growers that treated crops cannot be harvested until the tolerance is set and, if a tolerance is not issued, that the crop may not be harvested.

California issues about 30 to 40 Section 18s annually.

Minor-Use Crops: Section 18s and Section 24(c)s are issued mainly for “minor-use” crops. A “minor use” is generally agreed to be any use of a pest control product for which the sales value is insufficient to justify the cost by a commercial registrant to obtain and maintain a registration, particularly the costs associated with data generation and submission. A minor use may be the frequent use of a product on a low-acreage, specialty crop or the infrequent or localized use of a product on a high-acreage crop. In either case, the problem of obtaining a registration for the minor crop is primarily one of economics. As research and development costs for meeting regulatory requirements increase, pesticide registrants concentrate their registration efforts in areas where financial returns justify the costs. Thus, a registrant may choose to delete minor uses from a product label, or not register minor uses, rather than provide data to support registration.

Minor use pesticide registrations include most pesticide uses on fruit, nut and vegetable crops, as well as uses on commercially grown flowers, ornamentals, trees and turf grass. For many states, including California, minor crops make up a significant portion of all crop sales.

The great number of crops grown here, the diverse geography and weather, and the multiple growing seasons make the use of Section 18s and 24(c)s important in this state. The Pesticide Registration Branch manages review and evaluation for both Section 18 and Section 24c applications.

Comparing Section 18s and Section 24(c)s

Section 18

- Provides an exemption from registration requirements; tolerance must be set
- For limited use to treat sudden and limited emergency pest infestations
- Request from “third parties” only (grower groups, County Agricultural Commissioners, or universities)
- Request made through DPR, issued after approval by U.S. EPA; DPR may issue “crisis” Section 18 after consultation with U.S. EPA
- Can be used during the 30-day public comment period
- Issued for up to one year. Renewable if the emergency recurs or persists (although renewal difficult after the third year)
- Not subject to U.S. EPA maintenance fee
- Use requires a restricted material permit even if product is not a restricted material

Section 24(c)

- Provides a special registration, with a tolerance already in effect
- To meet a special local need (which may be a region of the state or the whole state)
- Requests from “first parties” (registrants) as well as third parties
- DPR issues without U.S. EPA review, although U.S. EPA may rescind
- Must be posted for the 30-day public comment period before use is allowed.
- Has no expiration date, although it may be withdrawn by the registrant, U.S. EPA, or DPR
- Subject to U.S. EPA maintenance fee
- Use requires a permit only if the product is a restricted material

For both:

- No feasible alternative is available
- Manufacturer must authorize access to its toxicology, residue, chemistry, and efficacy data.
- Chemical may or may not be registered for other uses

The great number of crops grown in California, the diverse geography and weather, and multiple growing seasons make Section 18s and 24(c)s important to the State.

